REMARKS

Claims 12, 14, 15 and 39 are pending. No amendments to the claims are made in this response. Reconsideration and immediate allowance of the pending claims in view of the remarks below is respectfully requested.

The Invention is Useful to Treat Prostate Cancer

Claims 12, 14–15, and 39 were rejected under 35 U.S.C. § 101 because the claimed invention allegedly is not supported by either a specific and substantial asserted utility or a well established utility. Applicants traverse this rejection and again assert that the claimed protein is useful as a target for antibodies on prostate cancer cells. The Examiner insists that because Applicants have not shown a difference in expression levels of the claimed protein in normal prostate cells versus cancerous prostate cells, the utility requirement has not been satisfied. As previously explained, questions relating to expression levels of the claimed protein on normal cells are not relevant to the issue of utility because Applicants have demonstrated that the claimed protein is detected on cancerous prostate cells. As such, Applicants' asserted utility has been demonstrated.

The Claimed Invention Has a Specific and Substantial Utility

The claimed polypeptide has a specific and substantial utility as a therapeutic marker for cancer cells and is therefore patentable. Under 35 U.S.C. § 101, a patent may be granted to "whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter." An invention may be useful for "any particular practical purpose (i.e., it has a "specific and substantial utility)." MPEP § 2107. The Federal Circuit has defined specificity as "particular to the subject matter claimed" and "not applicable to a broad class of invention." *In re Fisher*, 421 F.3d 1365, 1372 (Fed. Cir. 2005) (citing MPEP § 2107.01). For example, a specific utility could exist "where an applicant discloses a specific biological activity and reasonably correlates that activity to a disease condition." MPEP § 2107.01. In addition to being specific, an invention's utility must be substantial, where "a substantial utility defines a 'real world' use." *In re Fisher*, 421 F.3d at 1372. "*Any reasonable use* that an applicant has identified. . . that can be viewed as providing a public benefit should be accepted as sufficient, at least with regard to defining a

'substantial' utility." MPEP § 2107.01 (emphasis added); *see also Nelson v. Bowler*, 626 F.2d 853, 856 (CCPA 1980).

An invention's "specific benefit" must also be in "currently available form." *Brenner v. Manson*, 148 U.S.P.Q. 689 (1966). In *Brenner*, the invention was a process for producing a novel hormone where the hormone's only utility was its potential role as an object of use-testing. The court held that the process was patentable only if the hormone itself had a specific and currently available benefit. However, this does not "mean that products or services based on the claimed invention must be 'currently available' to the public in order to satisfy the utility requirement." MPEP § 2107.01.

The applicant benefits from a presumption that his assertion of utility is correct. In *In re Brana*, 51 F.3d 1560, 1562 (Fed. Cir. 1995), the applicants claimed compounds for use as antitumor substances. The Federal Circuit reversed the Board's affirmation of the examiner's rejection, finding that the PTO did not meet its "initial burden of challenging a presumptively correct assertion of utility in the disclosure," and that "[t]he purpose of treating cancer with chemical compounds does not suggest an inherently unbelievable undertaking or involve implausible scientific principles." *Id.* at 1566.

Here, Applicants have asserted a specific, substantial utility—namely, that of indicating and treating prostate cancer. The claimed polypeptide is a marker on cancerous prostate cells and is useful as a therapeutic target for antibodies directed against such cancer cells. This utility is indeed specific to the polypeptide claimed and not applicable to a broad range of inventions, which may or may not be expressed by cancerous prostate cells. Moreover, like the example given in the MPEP, the claimed polypeptide has been correlated to a specific disease condition—prostate cancer. In fact, Applicants have demonstrated that the claimed protein is detectable on the surface of prostate cancer cells. The demonstrated presence of the claimed protein on the surface of cancerous prostate cells demonstrates that Applicants' asserted utility is specific and substantial.

The asserted utility is also substantial in that it provides a "real world use" for the claimed subject matter as a means for producing a treatment for prostate cancer. This use provides a genuine public benefit. The Examiner is reminded that the present lack of an immediately available

commercial treatment for cancer based on the claimed polypeptide does not render the invention useless under *Brenner*.

Finally, Applicants' asserted utility carries the presumption of correctness and the Examiner failed to meet his initial burden in challenging the utility of the claimed protein. The purpose of treating cancers with antibodies using markers such as the claimed protein is neither inherently unbelievable nor implausible and the Examiner has not raised sufficient evidence to demonstrate otherwise.

Applicants have Provided Sufficient Evidence to Support the Asserted Utility

Applicants have provided evidence that the claimed protein: (a) does not need to distinguish between cancerous and healthy prostate cells; (b) is expressed by cancerous prostate cells; and (c) can be used in conjunction with antibodies as an antitumor therapy.

To be useful, the claimed protein does not need to distinguish between cancerous and health prostate cells. Moreover, the claimed protein need not be overexpressed in cancerous prostate cells vs. normal prostate cells. All that need be shown is that the protein is expressed at all on cancerous prostate cell for the claimed protein to be useful. This is because once a diagnosis of prostate cancer is made the elimination of cancerous prostate cells becomes a paramount interest.

The loss normal prostate cells while eliminating cancerous prostate cells is inconsequential from the point of evaluating utility. All that Applicants need to show to satisfy the utility requirement is that it is more likely than not that cancerous prostate cells will be killed using antibodies generated from the claimed protein. Those of ordinary skill in the art recognize that a human male can live without a prostate, a position supported by the common practice of surgically removing cancerous prostates from individuals diagnosed with prostate cancer. Furthermore, there are a number of antitumor antibodies on the market that cross react with normal tissue including Erbitux® and Rituxan®. Thus, as long as it can be shown that the target protein is detectable by antibodies made

Applicants have demonstrated that the claimed protein is expressed by cancerous prostate cells. Data supporting this point are found in the specification in the form of mRNA expression (*see*

Figs. 4, 5, and 6) as well as in the Rule 1.132 declaration of Dr. Morrison, which was provided with the Oct. 12, 2005 response. Dr. Morrison's declaration clearly demonstrates that antibodies which bind to the claimed protein are capable of binding prostate cancer cells

The specification also teaches the effects of an antibody alone or labeled with toxins, radioisotopes, or other chemotherapeutic agents for inhibiting the grown of prostate cancer cells expressing the claimed protein. Specification, page 56, line 1 to page 60, line 8.

The Examiner states, "The fact patterns involved between the commercially available antibodies and those which may be produced by the claimed polypeptide are different." Office Action, p. 6. Essentially, the Examiner claims that the commercially available antibodies have been discovered, while antibodies which may be produced by the claimed protein have not. However, this fact does not strip the claimed protein of utility under 35 U.S.C. § 101. Like the claimed compounds in *Brana*, the protein claimed here provides a plausible target for anti-cancer treatments, namely monoclonal antibodies. Treating cancer with monoclonal antibodies "does not suggest an inherently unbelievable undertaking or involve implausible scientific principles." To date, there are at least eight monoclonal antibody cancer therapies available on the market: Rituxan®, Herceptin®, Avastin® (Genentech), Mylotarg® (Wyeth), Campath® (Genzyme), Zevalin® (Biogen Idec), Bexxar (GlaxoSmithKline) and Erbitux® (ImClone).

The Examiner further cited the unpredictability of cancer therapies as underscored by Gura (Science, v278, 1997, pp. 1041–1042). Office Action, p. 6. What the Examiner failed to acknowledge is that development of cancer therapies, particularly cancer therapy using monoclonal antibodies, has progressed dramatically in the nine years since Gura's article was published. The first monoclonal antibody cancer therapy, Rituxan®, was approved in 1997, the year Gura's article was published. Since that time seven other monoclonal antibody cancer therapies have made it to the market, rendering Gura's article irrelevant to the utility of the claimed protein.

The Office has not stated a *prima facie* case

The Office has not made a *prima facie* showing that one of ordinary skill in the art would reasonable doubt that the claimed protein is useful as a therapeutic target. When making a rejection for an alleged lack of utility, the Office must make a *prima facie* showing that the claimed invention

lacks utility and it must provide sufficient evidence to support the basis of that *prima facie* showing. *In re Gaubert*, 524 F.2d 1222, 1224 (CCPA 1975); MPEP § 2107.2. In contrast, Applicants need only disclose a single specific and substantial utility to satisfy the requirement of the statute. *In re Fisher*, 421 F.3d 1365, 1370 (Fed. Cir. 2005).

Notwithstanding Applicants efforts to illuminate this issue, the Examiner continues to insist that there be some differential in expression of the claimed protein between normal prostate cells and cancerous prostate cells. This position is incorrect and irrelevant. Applicants have shown data which indicates that the claimed protein can be detected on the surface of cancerous prostate cells. Nothing more need be shown to satisfy the utility requirement. Accordingly, Applicants respectfully request that the present reject be withdrawn and the present case be passed to issuance.

Deposit Issue

Claims 14, 15, and 39 remain rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the enablement requirement. Applicants note that claim 39 make no reference to biologically deposited material and thus should not be included with the scope of the present rejection.

The Examiner has required that a specific statement to satisfy the deposit requirement. Applicants do not agree with the Examiner that such a formalistic recitation is required. Nevertheless, Applicants state that the deposited material will irrevocably and without restriction or condition be released to the public upon the issuance of a patent. As such, this rejection is overcome and should be withdrawn.

CONCLUSION

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejection of the claims and to pass this application to issue. If it is determined that a telephone conference would expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the number given below.

In the event the U.S. Patent and Trademark office determines that an extension and/or other relief is required, applicant petitions for any required relief including extensions of time and authorizes the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to Deposit Account No. 03-1952 referencing docket no. 511582000100. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

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Respectfully submitted,

By _____

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